REMARKS

Applicant appreciates the Examiner's thorough examination of the subject application and requests reconsideration of the subject application based on the following remarks.

Claims 1-25 are pending in the subject application. Claims 1-10, 17-20 and 22-25 stand rejected under 35 U.S.C. §102(e) as being anticipated by Bachand et al. Claims 11-13, 15-16 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bachand et al.

1. 35 U.S.C. §102 Rejections

Claims 1-10, 17-20 and 22-25 have been rejected under 35 U.S.C. §102(e) as being anticipated by Bachand et al. The Office refers to paper 4, in which the Office asserts that:

> Bachand et al teach a specimen collecting and testing device having an elongated hollow housing with a test membrane (21), a fluid chamber (26), an elongated handle (33) with an absorbent member (32) for collecting the sample. The handle (33) is pulled through slot (36) into expressor port (20) where the sample is squeezed from the member (32) [see page 3 column 1].

Applicant respectfully traverses this rejection.

Applicant claims in claim 1 a specimen collecting and testing device. Applicant's device includes (a) **an elongate, hollow housing** having a proximal end and a distal end; (b) at least one test membrane or sample collecting **strip positioned within the housing**, the test membrane carrying diagnostic test chemistry; (c) a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip; (c) at least one elongate handle member, having a proximal end and a distal end, **slidably received in the housing**; and (d) a foam member, for collecting specimen, extending from the proximal end of the handle. According to Applicant's invention, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip.

The Bachand reference, on the other hand, describes a saliva testing and confirmation device that includes an expressor cup 14 mounted on a testing and confirmation platform. A test strip 21 is mounted in the platform. According the Bachand, a collection swab is used to collect a specimen. The swab is then inserted into the expressor cup 14 where it is compressed, causing specimen to flow onto test strip 21.

Applicant respectfully submits that the Bachand reference describes a very different device and method than that taught by Applicant. Applicant teaches a integral collection and testing device that is easy to use. Applicant's device comprises an elongate, hollow housing that holds the components necessary to collect a sample and extract and test the collected sample. Applicant's device is a hand-held housing wherein the housing is picked up, including the sample collecting means, a means for extracting the sample from the sample collecting means and the sample testing strip. A handle, which has a foam member for collecting a sample, is slidably mounted in the housing such that when the handle is in a first position, the foam member is extended for sample collection. When the handle is pulled through the housing in a second position, the sample is extracted from the foam member and onto the test strip. Not only is Applicant's device easy to use, but it is also an integral device that is compact and easily portable. Because all of the components necessary to collect, extract and test a sample are contained in the single device, a plurality of components do not need to be carried about and put together for use. Further, it is very simple to use the device - one simply (1) positions the handle with the foam member extending out the proximal end of the housing by sliding the handle towards the proximal end of the housing, (2) collects a sample on the foam member, (3) slides the handle towards the distal end of the housing.

The Bachand reference, on the other hand, describes a multi-component device. Bauchand describes a platform that has mounted on it a cup and a test strip. During use, the platform is placed on a surface, such as a table. A swab or similar sample collection device is first used to collect a sample. The swab must then be inserted into

the cup on the platform. The cup is then used to express the sample from the swab and deposit the sample onto the test strip on the platform.

Applicant respectfully submits that the Bachand reference does not describe or otherwise suggest (a) an **elongate, hollow housing** having a proximal end and a distal end. Further, Applicants respectfully submit that the Bachand reference does not describe or otherwise suggest (b) at least one test membrane or sample collecting strip positioned **within the housing**. Still further, Applicants respectfully submit that the Bachand reference does not describe or otherwise suggest (d) an elongate handle member **slidably received in the elongate hollow housing**. Further, Applicant respectfully submits that the Office does not point to proof of such elements in the Bachand reference.

Regarding element (a), the Office merely states that "Bachand et al teach a specimen collecting and testing device having an elongated hollow housing with a test membrane (21)". In this assertion, the Office points to a test membrane (21) but does not point to an elongated hollow housing, as required by Applicant's claim 1. Further, nothing in the figures resembles an elongate hollow housing and nothing in the specification describes an elongate hollow housing. Rather, Bachand merely shows a platform with an expressor cup mounted thereon.

Regarding element (b), the Office merely states that "Bachand et al teach a specimen collecting and testing device having an elongated hollow housing with a test membrane (21)". However, as set out above, the Bachand reference does not describe an elongate hollow housing. Further, Bauchand does not describe or otherwise suggest "at least one test membrane or sample collecting strip positioned within the housing", as required by Applicant's claim 1. Rather, the Bauchand reference shows and describes a test strip (21) mounted on a platform (16).

Regarding element (d) the Office merely states that "Bachand et al teach a specimen collecting and testing device having... elongated handle (33)... The handle (33) is pulled through slot (36) into expressor port (20) where the sample is squeezed

form the member (32)." However, as set out above, the Bachand reference does not describe an elongate housing. Further, the Bachand reference does not describe "an elongate handle member slidably received in the elongate hollow housing", as required by Applicant's claim 1. Rather, the Bauchand reference shows a collection swab having a teather (33) ("handle"). The collection swab can be inserted into expressor cup (14) by sliding the teather (33) downwards through the slot. However, the cup 14 is not an elongate hollow housing as required by Applicant's claim 1.

In the event that the Office asserted that the cup (14) could somehow be considered to be an elongate hollow housing, this assertion would expressly confirm the fact that the Bachand reference does not have element (b), "at least one test membrane or sample collecting strip positioned within the housing." The test strip (21) is mounted in the platform (16) of the Bauchand device, not within the cup (14).

Unlike the Bachand reference, Applicant's device is an integral specimen collecting and testing device. A single device is used to collect the specimen and test the specimen. Applicants accomplish this by providing a handle having a foam member mounted thereon for collecting the sample. The handle is slidably mounted in the elongate hollow housing. The elongate hollow housing contains all of the components necessary for testing the sample. Thus, one would simply and conveniently use Applicant's device by picking up the entire device, including the handle and foam member and the housing and components necessary for testing the sample. The sample is collected on the foam member and the handle is simply pulled through the housing to deposit the sample on the test strip within the housing.

The Bachand reference, on the other hand, describes a platform having a expressor cup and sample strip mounted thereon. The platform includes the components necessary for testing the sample. A separate swab or other type of fluid collection element would then be used to collect a sample. The swab of the Bachand reference is not slidably mounted to the platform, unlike Applicant's handle which is slidably mounted within Applicant's housing. The platform, rather, is a stationary element that is mounted on a surface, such as a table, during use. The platform, by

its design, could not feasibly be picked up along with the swab for collection of a sample as Applicant's housing is picked up along with the handle for collection of a sample. Thus, one would use the Bachand device by taking a swab or other type of fluid collection element to collect a sample. The swab is then inserted into the expressor cup of the platform so that the sample can be deposited on the test strip.

Applicants further claim in claim 22 a method of collecting a sample of fluid specimen for diagnostic testing. Applicant's method comprises (a) providing a specimen collecting and testing device which includes **an elongate, hollow housing** having a proximal end and a distal end; at least one test membrane or sample collecting **strip positioned within the housing**, the test membrane carrying diagnostic test chemistry; a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip; an aperture in the fluid chamber positioned adjacent to the test membrane or sample collecting strip; at least one elongate handle member, having a proximal end and a distal end, **slidably received in the housing**; and a foam member, for collecting specimen, extending from the proximal end of the handle; (b) wetting the foam member with specimen; (c) **positioning the device vertically with the foam member extending upwards**; (d) sliding the handle member through the housing, thereby drawing the wetted foam member across the fluid chamber and delivering the collected specimen to the fluid chamber; (e) and positioning the device horizontally so as to level off the specimen in the fluid chamber and allow the specimen to flow through the aperture and onto the test membrane or sample collecting strip.

Applicant respectfully submits that the device and method described by the Bachand reference is very different than that taught by Applicant. As set out above, Bachand describes a saliva testing and confirmation device that includes an expressor cup mounted on a testing and confirmation platform. A test strip is mounted on the testing and confirmation platform. According the Bachand, a collection swab is used to collect a specimen. The swab is then inserted into the expressor cup where it is compressed, causing specimen to flow onto test strip. As set forth above, the Bachand device does <u>not</u> describe or suggest an elongate hollow housing. Further, the Bachand

reference does not describe a test membrane or sample collecting strip positioned within the housing or a handle slidably received within the housing. Further, the Bachand reference does not describe a method of collecting a sample wherein (c) after the sample is collected, the device (i.e. the elongate hollow housing having the handle with foam member slidably received therein, the test membrane mounted therein and the fluid chamber positioned adjacent to the test membrane) is positioned vertically with the foam member extending upwards or (e) and positioning the device horizontally so as to level off the specimen in the fluid chamber and allow the specimen to flow through the aperture and onto the test membrane or sample collecting strip.

Rather, the Bachand device includes a platform which has a test membrane mounted thereon and a cup mounted thereon. The swab is used to collect a sample, and the swab is then inserted into the cup. The platform and cup are stationary objects which are not designed or capable of being picked up (with the swab in the cup) during collection of the sample or vertically held with the foam member extending upwards. Rather, the swab is inserted into the cup, with the "foam" portion (the collection portion of the swab) extending down so that the sample expressed can pass into the test well(s) 26, 26' and into the confirmation means 18. In this position, the swab could not access a site for sample collection (See Fig. 4, which shows the swab in the cup) because the design on the platform would block the swab's access to a collection site. Further, the platform and cup have a design that does not make it practical or possible to pick up during collection or hold vertically during sample extraction from the swab.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identity

of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

It is clear from the foregoing remarks that claims 1 and 22 are not anticipated by the Bachand et al. reference. Claims 2-10 and 17-20 depend from claim 1 and, likewise, are not anticipated by the Bachand et al. reference. Claims 23-25 depend from claim 22 and, likewise, are not anticipated by the Bachand et al. reference.

2. 35 U.S.C. §103 Rejections

Claims 11-13, 15-16 and 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bachand et al. The Office refers to paper 4, in which the Office asserts that:

> Bachand et al. is silent to the material of absorbent member, the material of the handle and if the handle is hollow and the use of preservatives...
> ...It is also known to make handles hollow to achieve the well known and expected results of reducing cost of manufacture and shipping weight. It would have been within the skill of the art to modify Bachand et al. and to use a preservative and a hollow handle as optimization of a result effective variable to gain the above advantages.

Applicant respectfully traverses this rejection for the same reasons as set out above.

In particular, Applicant claims in claim 1 a specimen collecting and testing device. Applicant's device includes (a) **an elongate, hollow housing** having a proximal end and a distal end; (b) at least one test membrane or sample collecting **strip positioned within the housing**, the test membrane carrying diagnostic test chemistry; (c) a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip; (c) at least one elongate handle member, having a proximal end and a distal end, **slidably received in the housing**; and (d) a foam member, for collecting specimen, extending from the proximal end of the handle. According to Applicant's invention, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip.

As set out above, the Bauchand reference fails to describe or otherwise suggest a) **an elongate, hollow housing** having a proximal end and a distal end. Further, Applicants respectfully submit that the Bachand reference does not describe or otherwise suggest (b) at least one test membrane or sample **collecting strip positioned within the housing.** Still further, Applicants respectfully submit that the Bachand reference does not describe or otherwise suggest (d) an elongate handle member **slidably received in the elongate hollow housing**. Further, Applicant respectfully submits that the Office does not point to proof of such elements in the Bachand reference.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

As clearly set out above, the Bachand reference does not teach or suggest all the claim limitations. Further, there is no suggestion or motivation to modify the reference as required by Applicant's claim 1.

Accordingly, claim 1 is patentable over the Bachand et al. reference. Claims 11-13, 15-16 and 21 depend from claim 1 and, likewise, are patentable over the Bachand et al. reference.

CONCLUSION

Reconsideration and allowance of claims 1-25 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

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